CTRNet Standard Operating Procedure Clinical Annotation			
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Approved By:	CTRNet Management Group (CMG)	01-May-2012
	Per: Brent Schacter	31-May-2012

1.0 PURPOSE

Tissue donated to the tumour biobank is intended for research studies. The success of translational research, and ultimately personalized medicine, depends on the ability to forge a connection between phenotypic clinical data and molecular measurements on samples. The efficient integration of clinical data with scientific results has become critical in determining populations of patients that may best benefit from a new drug or therapy. Standardized and complete data capture provides the best hope for analyzing large data sets, over many institutions, and will allow comparisons with other similar or collaborative studies.

2.0 SCOPE

This standard operating procedure (SOP) covers the procedures to ensure that consistent and high-quality data is associated with samples in the biobanks.

These steps may be adopted as is, or modified by specific CTRNet member biobanks at their collection sites to allow for the incorporation of site-specific details, local laws and regulations, conditions and Research Ethics Board (REB) requirements.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

Note: When adopting this SOP for local use please reference CTRNet.

3.1 *CTRNet Policy: POL 5 Records and Documentation*

3.2 *CTRNet Policy: POL 7 Material and Information Handling*

4.0 ROLES AND RESPONSIBILITIES

The SOP applies to all qualified tumour biobank personnel, clinical and research staff at the collection centers and biobanks that are involved in clinical annotation of samples.

Tumour Biobank Personnel	**Responsibility/Role**
Tumour Biobank or Research Principal Investigator, Tumour Biobank Director and Consulting Physician	Determining the range of clinical data that will be collected for a sample
REB	Reviewing and deciding if sensitive clinical data should be collected
Nurses, technicians/technologists and database analysts	Collecting and managing clinical data.

5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site- specific task or procedure.

Materials and Equipment	Materials and Equipment (Site Specific)
Health records, Pathology Reports	
Patient Questionnaires	
Inventory and specimen database	

6.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/glossary

7.0 PROCEDURES

The primary goal of the tumour biobanks is to facilitate research that can advance the practice of oncology and preventive medicine. Extensive and consistent annotations of the specimens are crucial to the overall value of the biobanked samples in research studies.

7.1 Determining the Clinical Data Set

7.1.1 Define the minimum clinical data to be collected for all biospecimens. Note that this set may be subject to change over time, and may depend on the particular research study.

7.1.2 Use harmonized terminology or Common Data Elements to describe data being collected to facilitate data sharing and universal understanding.

7.2 Collecting and Management of Clinical data

7.2.1 Data collection should strive to conform to requirements stipulated by regulatory agencies and/or by internationally recognized standards.

7.2.2 Track researchers requests for specific data to guide the extent of collection of data in the future.

7.2.3 Only collect data if adequate consent procedures are in place.

7.2.4 Have a method of validating data collected so as to ensure accuracy.

7.2.5 In linking and annotating samples comply with privacy regulations and participant protection.

7.2.6 Maintain identifying and contact information as permitted under privacy law to enable the specimen to be useful for longitudinal studies.

7.2.7 Attempt to collect outcome data with tracking of treatment and patient outcomes.

7.2.8 Use only trained personnel to collect, enter, transfer and validate clinical data.

7.3 Specific Clinical Annotation

The following data about specimen and participant represents examples of the type of data that is valuable to collect.

7.3.1 Demographic data
- Date of birth
- Race/Ethnicity
- Place of Birth
- Physician
- Contact information (when approved by the consent)

7.3.2 Lifestyle Factors

7.3.3 Family History

7.3.4 Epidemiological risk factors
- Alcohol Data
- Smoking Data
- Environmental and occupational exposure

7.3.5 Patient's medical history

7.3.6 Patient's cancer history, including family history

7.3.7 Pathology data
- Diagnosis data
- Histology
- Site, Stage, grade, size

7.3.8 Pertinent diagnostic studies (Biomarkers like PSA etc.)

7.3.9 Information on initial staging procedure

7.3.10 Treatment data
- Type (chemotherapy, Radiation, Other)
- Dose
- Therapeutic Agent name

7.3.11 Response to Treatment

7.3.12 Surgery Data
- Type of Surgery
- Margin status

7.3.13 Follow-up data/Outcome data
- Vital status

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Declaration of Helsinki
http://www.wma.net/en/30publications/10policies/b3/index.html

8.2 International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, section 4.8.
http://www.ich.org/products/guidelines.html

8.3 Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials. Division 5. Canada Gazette Part II, Vol. 135, No. 13, June 7, 2001 Section C.05.010 Sponsor Obligations
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

8.4 Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

8.5 USA Food and Drug Administration FDA Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects
http://www.fda.gov/oc/gcp/default.htm or
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

8.6 Fox Chase Cancer Centre, Biosample repository
http://www.fccc.edu/prevention/studies/biosample/

8.7 First Generation Guidelines for NCI-supported Biorepositories, Federal Register/ Vol.71, No 82/ April 28, 2006

8.8 Patel, A. et al. 2005, The development of common data elements for multi-institute prostate cancer tissue bank: The cooperative Prostate cancer Tissue Resource (CPCTR) experience. BMC Cancer, 5:108.

9.0 APPENDICES

None

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions
2.1.006	2008	JdSH	1st Release.
3.1.004 e1.0	May 2012	CMG	• Grammatical and formatting throughout • Definitions removed • Revision History moved to bottom • Reference links updates • Updated SOP references • Section 1: Purpose, last sentence deleted. • Section 7.2: Deleted “such as the FDA so that data can be cited and used in drug approval submissions”. • Section 7.3: Revised demographic data collection